REMARKS

Applicants have amended the claims to more particularly define the invention taking into consideration the outstanding Official Action.

Applicants have amended claim 1 to further define the invention to include the biocompatible polymer as fully supported by the specification as originally filed, see page 6, fourth full paragraph. Claims 18 and 19 have been amended to correct the dependency in view of the cancellation of claim 17. New claim 72 has been added to a further aspect of the invention as supported by the specification as originally filed and is a combination of dependent claims. Applicants have canceled claim 17 and have amended claims 1 and 18-19 in the present application. Applicants have canceled claims 21-71 from the present application as being drawn to a non-elected invention. Applicants retain their right to file a divisional application at a later time.

Applicants submit that all of the claims now present in the application are fully supported by the specification as originally filed and no new matter is introduced.

Applicants most respectfully submit that all of the claims now present in the application are in full compliance with 35 USC 112 and clearly patentable over the references of record.

Applicants note that the receipt of the Information Disclosure Statement dated March 29, 2005 is acknowledged.

The rejection of claims 1 and 3 under 35 USC 102(b) as being anticipated over Willi Paul et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the following comments.

Applicants wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir.

> 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 1, 3-5, 10, 11, 14 and 17 under 35 USC 102(b) as being anticipated over Tsuru et al. et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the following comments.

The "porous granules of a calcium phosphate compound" in Tsuru, for example, the porous hydroxyapatite granules used in Examples 1-4, 6-7 and "porous tricalcium phosphate (TCP)" in Example 5 of D1, is not the "porous apatite grains" recited in claim 1 of the present application, because the former is a porous calcium phosphate compound prepared by firing at a temperature of 200-1400°C, preferably 500-1300°C, and more preferably 700-1200°C with a forming agent or a particulate substance capable of being dissipated upon heating (page 3, lines 14-30); and the latter is prepared by incubation of wetted granules of a slurry containing particles of a calcium source and particles of a phosphate source (please see claims 21 or 48 of the present application). The firing treatment used in Tsuru not only will cause integration of the calcium phosphate compound (particles) (a disintegration step is required to obtain the desired granule size (see page 3, bottom line to page 4, line 2)), but will form pores mainly from the vanishment of the forming agent or the particulate substance capable of being dissipated upon heating, e.g. Example 6 of Tsuru. The firing treatment will stop the fired calcium phosphate compound to undergo an apatite-forming conversion reaction when the fired particles contact water. Therefore, the drug is adsorbed and sucked in the pores of the fired porous calcium phosphate particles in Tsuru. In the present invention the drug is entrapped in the pores of porous apatite grains, because the drug is adsorbed and sucked in the pores while apatite-forming conversion reaction is undergoing.

The polymer used by Tsuru as disclosed in page 4, lines 45+, is for lowering the specific gravity of the calcium phosphate granules, which is done by coating the polymer on the calcium phosphate granules after the calcium phosphate granules being

formed. On the contrary, the biocompatible polymer is located among the porous apatite grains to bind them into a microspherical composite in the subject invention. This microspherical composite structure is prepared by special processes as recited in claims 40 and 66 of the present application.

The major difference between Tsuru and the newly amended claim 1 of the present application is the former discloses a porous calcium phosphate compound bulk and disintegrate the bulk into porous granules which can be further coated with a polymer, and the latter discloses a microspherical composite composed of porous apatite grains bounded by a polymer in the a microspherical composite and among the porous apatite grains. The biocompatible polymer recited in the newly amended claim 1 is important, which binds the apatite grains to form the microspherical composite with an improved strength, and avoid the cracking of the microspherical composite during the stirring or fluidizing. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 1-15 under 35 USC 103(a) as being unpatentable over Masuno Ichirou in view of Willi Paul et al. and further in view of Tsuru et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the above and following comments.

Masuno is not close to the subject invention, because it discloses a porous substance of hydroxycalcium apatite or a natural high polymer. As recited in claim 2 of Masuno the porous substance of hydroxycalcium apatite is a calcined hydroxycalcium apatite, and this is not close to the porous apatite grains of the subject invention as explained in above 1). Willi Paul et al prepare hydroxyapatitie nanparticles by firing CHA (chitosan-HA) particles at 800°C for one hour to remove chitosan. (Please see page 2, lines 18-29, "Materials & Methods"). That means the hydroxyapatitie nanparticles disclosed by Willi paul et al are not porous apatite grains as recited in the newly amended claim 1 as explained in above 1). Moreover, these are not obvious to one of ordinary skill in the art to which the invention pertains. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 17-20 under 35 USC 103(a) as being unpatentable over

Masuno Ichirou in view of Willi Paul et al., Tsuru et al. and further in view of Sapiezsco et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the above and following comments.

Sapiezsco is not close to the subject invention because it discloses a porous scaffold structure, which is not porous apatite grains of the subject invention. This porous scaffold structure in Sapiezsco may be imbibed with biosasorbable polymer or film-forming agent such as PGA, PL_PA (see col. 24, lines 31+), which is not a microspherical composite composed of porous apatite grains bounded by a polymer in the a microspherical composite and among the porous apatite grains. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claim 16 under 35 USC 103(a) as being unpatentable over Masuno Ichirou in view of Willi Paul et al., Tsuru et al., and further in view of Troczynski has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the above comments. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above comments and further amendments to the and claims, favorable reconsideration and allowance of all the claims now present in the application are most respectfully requested.

Respectfully submitted,
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